

**AMENDMENTS TO THE DRAWINGS**

The attachment to this Amendment includes three (3) sheets of replacement drawings (Figs. 1-3). The replacement drawings are formal figures. Please substitute the replacement drawings for the original drawings in the following manner.

<b>Replacement Drawings</b>		<b>Original Drawings</b>
Sheet 1 (Fig. 1)	<i>replaces</i>	Sheet 1 (Fig. 1)
Sheet 2 (Fig. 2)	<i>replaces</i>	Sheet 2 (Fig. 2)
Sheet 3 (Fig. 3)	<i>replaces</i>	Sheet 3 (Fig. 3)

### **REMARKS**

The above Amendment and the following remarks are responsive to the Office Action dated January 3, 2007. The Applicant requests entry of this Amendment, favorable reconsideration of this case, and early issuance of a Notice of Allowance.

#### **Status of the Claims**

Upon entry of this paper, the Applicant has rewritten claims 1 and 10-13. Thus, claims 1-14 are pending in the application of which claims 1 and 10 are written in independent form.

#### **Response to the Objections to the Drawings**

The Examiner objected to the drawings because they include the reference characters "240", "260", and "280" that are not mentioned in the description. In response, the Applicant has amended paragraphs 00019, 00021, 00022, and 00024 to include reference characters 240 and 280, and to replace reference character 300 with reference character 260. Correction to the drawing sheets was not necessary to respond to this objection. Thus, the Applicant believes that the Examiner should withdraw this objection to the drawings.

The Examiner also objected to the drawings because they include the reference characters "300" and "310" that are not mentioned in the description. In response, the Applicant has amended paragraphs 00021, 00022, and 00024 to replace reference character 300 with reference character 260, and submits a replacement drawing for Fig. 3 which includes the reference character 310. Thus, the Applicant believes that the Examiner should withdraw this objection to the drawings.

The Examiner also objected to the drawings because Figure 1 should be designated by a legend to indicate that it illustrates the prior art. In response, the Applicant submits a

replacement drawing for Fig. 1 which includes the legend "Prior Art". Thus, the Applicant believes that the Examiner should withdraw this objection to the drawings.

### **Response to the Objections to the Disclosure**

The Examiner objected to paragraph 0005, line 13 of the Applicant's disclosure and requested removal of the "s" from "devices". In response, the Applicant has amended paragraph 0005 as requested by the Examiner. This amendment to the specification was necessary to correct typographical errors and does not introduce new matter. Thus, the Applicant believes that the Examiner should withdraw this objection to the disclosure.

The Examiner also objected to paragraph 00016, line 16 and paragraph 00017, line 1 of the Applicant's disclosure and requested insertion of character reference "10" after "absolute contraindications". In response, the Applicant has amended paragraphs 00016 and 00017 as requested by the Examiner. These amendments to the specification were necessary to correct typographical errors and do not introduce new matter. Thus, the Applicant believes that the Examiner should withdraw this objection to the disclosure.

The Examiner also objected to paragraph 00021, line 9, and paragraph 00023, line 6 of the Applicant's disclosure and requested insertion of character reference "270" after "customized dynamic informed consent form". In response, the Applicant has amended paragraphs 00021 and 00023 as requested by the Examiner however, the correction to paragraph 00021 was on line 3, not line 9. These amendments to the specification were necessary to correct typographical errors and do not introduce new matter. Thus, the Applicant believes that the Examiner should withdraw this objection to the disclosure.

The Examiner also objected to paragraph 00026, line 9 of the Applicant's disclosure and requested insertion of "be" between "would" and "appropriate". In response, the Applicant has

amended paragraph 00026 as requested by the Examiner however, the correction was on line 7, not line 9. This amendment to the specification was necessary to correct typographical errors and does not introduce new matter. Thus, the Applicant believes that the Examiner should withdraw this objection to the disclosure.

**Response to the Rejections under 35 U.S.C. § 102**

***Rejection of Claims 1-8, 10, and 12-14***

The Examiner rejected claims 1-8, 10, and 12-14 under 35 U.S.C. § 102(e) as being anticipated by Papageorge, United States Patent Number 6,584,445 (hereinafter "Papageorge"). The Applicants respectfully traverses this rejection.

Anticipation requires that each and every element of the claims must be present in the cited prior art reference. The Papageorge reference does not anticipate the claims, as amended.

The Papageorge reference describes a computerized health evaluation system. The system includes a patient module, a physician module, and a database of medical findings concerning a particular disease and condition. The patient module allows the patient to input lifestyle and preference data into the system. The physician module allows the physician to input physical and physiological data into the system. The system uses an algorithm to weigh the patient data and the physician data in view of the database and generate a report of various treatment options available for the patient. The patient and physician review the report, discuss the various treatments options available, and jointly decide upon a treatment approach.

In contrast, independent claims 1 and 10, as amended, describe a "computer-implemented process for informing a patient of the risks of undergoing a treatment". The process gathers data, calculates a "customized personal risk assessment" for the patient based on the gathered data, and presents the customized personal risk assessment to the patient as an "informed consent

form". Independent claims 1 and 10, as amended and the Papageorge reference differ in the following respects. First, the Papageorge reference does not describe a system that presents a customized personal risk assessment to the patient as an informed consent form as recited in independent claims 1 and 10, as amended. Second, the Papageorge reference describes a system that generates a report of various treatment options available for the patient. The patient and physician discuss the various treatments options available and jointly decide upon a treatment approach for the patient, thus permitting more informed treatment choices for the patient. In contrast, independent claims 1 and 10, as amended, recite a process for informing a patient of the risks associated with a particular treatment that the patient is "undergoing" and has contemplated. Third, the Papageorge reference describes a system that uses static data focused on medical economic aspects and cost effectiveness, rather than evolving data focused on risk reduction such as "other patients" prior experiences "as a result of undergoing the treatment" as recited in independent claims 1 and 10, as amended. For at least these reasons, the Examiner should withdraw this anticipation rejection based on the Papageorge reference as to claims 1 and 10, as amended.

Claims 2-9 and 11-14 depend from either independent claim 1 or 10. For the previously stated reasons, independent claims 1 and 10, as amended, are allowable. Since any claim that depends from an allowable independent claim is also allowable, the Applicants believe that the Examiner should withdraw this anticipation rejection based on the Papageorge reference as to dependent claims 2-9 and 11-14.

## **Response to the Rejections under 35 U.S.C. § 103**

### ***Rejection of Claims 9 and 11***

The Examiner rejected dependent claims 9 and 11 under 35 U.S.C. § 103(a) as being unpatentable over the Papageorge reference in view of Rakshit et al., United States Patent Number 5,799,282 (hereinafter “Rakshit”). The Applicants respectfully traverse these rejections.

The framework for an analysis of patentability under 35 U.S.C. § 103, that is determining whether an invention is nonobvious, is ultimately a matter of law, but that matter of law is informed by and depends upon factual matters that must be considered. The analysis requires consideration of four factors: (i) the scope and content of the prior art, (ii) the differences between the prior art and the claims as a whole, (iii) the level of ordinary skill in the art, and (iv) objective evidence of non-obviousness. *Graham v. John Deere*, 383 U.S. 1, 13 (1966). The analysis should avoid combining elements from different prior art references in hindsight.

For the reasons stated in the previous section titled “Response to the Rejections under 35 U.S.C. § 102”, the differences between the limitations recited in independent claims 1 and 10, as amended, and the Papageorge reference are nonobvious. Thus, a *prima facie* conclusion of obviousness cannot be drawn from the Papageorge reference taken alone.

The Rakshit reference describes a method for establishing certifiable patient informed consent for a medical procedure. The patient interacts with a video training system until measurable behaviors approximately coincide with the legal and medical standards for establishing informed consent.

In contrast, independent claims 1 and 10, as amended, describe a “computer-implemented process for informing a patient of the risks of undergoing a treatment”. The process gathers data related to the treatment and to other patients’ experiences during and after undergoing the

treatment to calculate a “customized personal risk assessment” for the patient. The process presents the customized personal risk assessment to the patient as an “informed consent form”.

Since the Rakshit reference does not describe the limitations of the process for informing a patient of the risks of undergoing a treatment as recited in independent claims 1 and 10, independent claims 1 and 10 are nonobvious over the Rakshit reference, taken alone.

Furthermore, since the Rakshit reference does not make up for the shortcomings of the Papageorge reference, independent claims 1 and 10, as amended, are nonobvious over the combination of the Papageorge and Rakshit references.

Claims 9 and 11 depend from independent claim 1 or 10. For the previously stated reasons, independent claims 1 and 10, as amended, are allowable. Since any claim that depends from an allowable independent claim is also allowable, the Applicants respectfully submit that the Examiner should also withdraw this rejection as to dependent claims 9 and 11.

Application Serial Number: 10/607,526  
1.111 Amendment dated May 2, 2007  
Reply to Office Action dated January 3, 2007

Attorney Docket Number: 043738-187273

**AUTHORIZATION**

The undersigned hereby authorizes the Commissioner to charge all required fees, fees under 37 C.F.R. §§ 1.16 and 1.17, or all required extension of time fees for this paper to Deposit Account Number 50-0573, Order Number 043738-187273.

Respectfully submitted,  
APPLICANT NAME



Kenneth P. Waszkiewicz  
Registration Number: 45,724  
DRINKER, BIDDLE & REATH, L.L.P.  
1500 K Street, N.W., Suite 1100  
Washington, DC 20005-12093

202-842-8823 – phone  
202-842-8469 – fax

Dated: May 2, 2007